

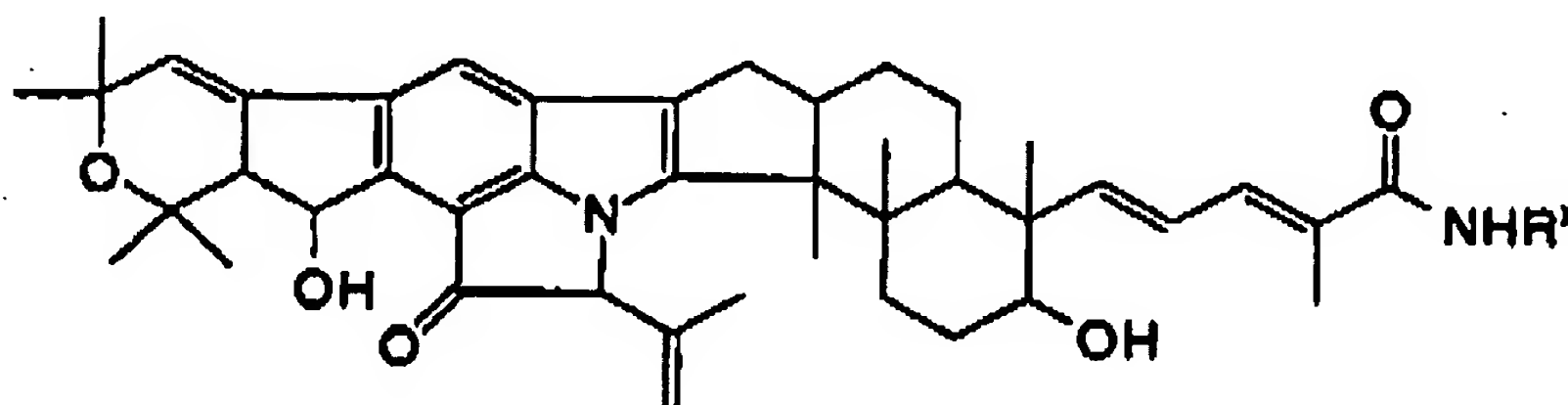
Application Serial No. 10/618,975

MER 03-009

REMARKS

Claims 1-63 are pending. Previously the applicants had elected to prosecute the invention of Group I, claims 1-24, 42-44 and 63 and elected the species of t-butyl nodulisporamide as the nodulisporic acid and transcitol as the specific liquid carrier. These elections were made with traverse.

In response to the Examiner's request for clarification about the structure of the t-butyl nodulisporic acid, the structure of this compound, wherein R^x is $C(CH_3)_3$, is shown below:



(see e.g., paragraphs [0499]-[0501] of the U.S. Patent Application Publication 2004-0077703 which corresponds to this application)

The election of the 5-butyl nodulisporamide with the above structure is made with traverse.

Reconsideration and withdrawal of the restriction requirement mailed March 23, 2006, July 12, 2006 and November 3, 2006 are respectfully requested in view of the remarks herewith.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP

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directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

In the restriction requirement mailed March 23, 2006, Groups I, II, III and IV are directed to formulations comprising spot-on formulation for the treatment or prophylaxis of parasite infestation in mammals or birds which comprises (1) an effective amount of at least one nodulisporic acid derivative (2) a pharmaceutically or veterinary acceptable liquid carrier vehicle; and (3) optionally, a crystallization inhibitor and methods of using the same. It is respectfully submitted that any search for the formulation of the Group I claims will certainly encompass methods of the Group II, Group III and Group IV claims as they all involve searches for the formulations of Group I. The four groups are inextricably linked in that the formulations are identical. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine all groups together, as a search for the Group I formulations would necessarily include the Group II, Group III and Group IV methods as the methods involve the formulations of Group I.

In the alternative, Groups I, II and III are all classified in the same class and subclass, namely class 514 and subclass 410. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine Groups I, II and III together, as they all involve searches in the same class and subclass.

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In the alternative, Groups I and IV are all classified in the same class and subclass, namely class 548 and subclass 417. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine Groups I and IV together, as they all involve searches in the same class and subclass.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

The July 12, 2006 Office Action called for species election of a specifically disclosed composition which included defining a specifically named or completely defined nodulisporic acid derivative and a specifically named or completely defined liquid carrier vehicle.

Claims 6 and 48, for example, are generic claims listing specifically named or completely defined nodulisporic acid derivatived or species of specifically named or completely defined liquid carrier vehicles as Markush groups. The Examiner is respectfully requested to review M.P.E.P. § 803.02 which states "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." Furthermore, in view of M.P.E.P. § 803, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

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In the instant case, there is a disclosure of relationship between the claimed species. Applicants' claims are directed to formulations comprising spot-on formulation for the treatment or prophylaxis of parasite infestation in mammals or birds which comprises (1) an effective amount of at least one nodulisporic acid derivative (2) a pharmaceutically or veterinary acceptable liquid carrier vehicle; and (3) optionally, a crystallization inhibitor. There is a disclosed relationship between the nodulisporic acid derivatives and pharmaceutically or veterinarily acceptable liquid carrier vehicles as they are all insect growth regulators which may be incorporated into the claimed formulation and methods of use.

Additionally, the claims are not broken into separate classifications on the basis of which species is claimed. Consequently, it can be assumed that the classification of all the claims into a single group was made considering each of the species, such that the search of any species would be co-extensive and include the remaining species.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed).

Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in

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any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction requirement are respectfully requested.

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CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement are requested.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

If any fee or extension of time is required to obtain entry of this Response, the undersigned hereby petitions the Commissioner to grant any necessary time extension and authorizes charging Deposit Account No. 502354 for any such fee not submitted herewith.

The Examiner is invited to contact the undersigned at 678-638-3805, at the Examiner's convenience, to resolve any issues concerning this Response.

Respectfully submitted,
Merial Ltd.

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4 Dec 2006

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